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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,395	02/25/2002	Frank Diehl	22012.PUS	4534
7590 11/04/2004				
Eugene E. Renz, Jr., P.C. 205 North Monroe Street Post Office Box 2056 Media, PA 19063-9056		EXAMINER FORMAN, BETTY J		
		ART UNIT PAPER NUMBER		
		1634		

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/082,395	Applicant(s) DIEHL ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 September 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 1 September 2004 in which claims 13 and 24-26 were amended. The amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 12 November 2003 under 35 U.S.C. 102 and 103 are maintained. **The previous requirement to comply with nucleic acid sequence rules is maintained.** All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Claims 13-26 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 13-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-26 are indefinite because they are drawn a process for covalently or electrostatically binding nucleic acids to a carrier. However, the claims do not recite method steps of covalent or electrostatic binding. Therefore, it is unclear whether the method steps accomplish the claimed method.

Claim interpretation

5. The claims are drawn to process of covalently or electrostatically binding nucleic acids to a carrier. The method steps include dissolving nucleic acids in a spotting solution comprising betaines and applying the solution onto a carrier. While the method steps define the solution as a "spotting solution" the method steps do not require a step of spotting. Hence, the claims are not interpreted as requiring a spotting step. Furthermore, while the methods are drawn to covalent or electrostatic binding, the method steps do not define the binding of step (b) as covalent or electrostatic. Hence, the claims are not so limited.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13, 15-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Diehl et al (Nucleic Acids Research, 2001, 29(7): e38, pages 1-5).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Regarding Claim 13, Diehl et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a composition comprising betaines and applying the solution onto the carrier (paragraph spanning pages 1-2).

Regarding Claim 15, Diehl et al disclose the process wherein the betaine is present at a concentration of 8m M to 6.5 M (page 1, last line).

Regarding Claim 16, Diehl et al disclose the process wherein the solution contains about 1.5M sodium chloride and about 150m M sodium citrate and the pH is about 7 (pages 1- 2).

Regarding Claim 17, Diehl et al disclose the process wherein the carrier is glass (last paragraph, page 1).

Regarding Claim 18, Diehl et al disclose the process wherein the glass is coated with poly-L-lysine (last paragraph, page 1).

Regarding Claim 19, Diehl et al disclose the process wherein after nucleic acid binding, the glass is treated to deactivate the poly-L-lysine i.e. blocking (page 2, first paragraph).

Regarding Claims 20-22, Diehl et al disclose the process wherein the glass is treated with succinic anhydride and an acylating catalyst i.e. n-methylimidazole in a nonpolar nonaqueiou solvent i.e. 1,2 dichloroethane (page 2, first paragraph).

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Regarding Claim 23, Diehl et al disclose the process wherein 0.2 g to 20 g succinic anhydride and 1ml to 10ml N-methylimidazole are dissolved in 200ml 1,2 dichloroethane (page 2, first paragraph).

Regarding Claim 24, Diehl et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a composition comprising betaines and applying the solution onto the carrier (paragraph spanning pages 1-2).

Regarding Claim 25, Diehl et al disclose a process for manufacturing microarrays comprising dissolving nucleic acids in a composition comprising betaines and applying the solution onto the surface of the microarray (paragraph spanning pages 1-2).

Regarding Claim 26, Diehl et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a composition comprising betaines and applying the solution onto the carrier (paragraph spanning pages 1-2).

8. Claims 13, 15, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Meade et al (U.S. Patent No. 5,824,473, issued 20 October 1998).

Regarding Claim 13, Meade et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a composition comprising betaines (i.e. triethylammonium acetate, TEAA) and applying the solution onto the carrier (Example 8, Column 33, lines 20-31) wherein the nucleic acids are covalently bound (Meade defines the attachment of Example 8 as covalent, see Column 26, lines 1-10).

Regarding Claim 15, Meade et al disclose the process wherein the betaine is present at a concentration of 8m M to 6.5 M (Column 33, lines 20-31).

Regarding Claim 24, Meade et al disclose a process for binding nucleic acids to a carrier comprising adding betaines (i.e. triethylammonium acetate, TEAA) to a solution of nucleic acids

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and applying the solution onto the carrier (Example 8, Column 33, lines 20-31) wherein the nucleic acids are covalently bound (Meade defines the attachment of Example 8 as covalent, see Column 26, lines 1-10)

Regarding Claim 25, Meade et al disclose a process for binding nucleic acids to a microarray (i.e. electrode matrix, Column 24, lines 31-40) comprising dissolving nucleic acids in a composition comprising betaines (i.e. triethylammonium acetate, TEAA) and applying the solution onto the carrier (Example 8, Column 33, lines 20-31) wherein the nucleic acids are covalently bound (Meade defines the attachment of Example 8 as covalent, see Column 26, lines 1-10)

Regarding Claim 26, Meade et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a composition comprising betaines (i.e. triethylammonium acetate, TEAA) and applying the solution onto the carrier (Example 8, Column 33, lines 20-31) wherein the nucleic acids are covalently bound (Meade defines the attachment of Example 8 as covalent, see Column 26, lines 1-10)

9. Claims 13-15, 17 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cronin et al (U.S. Patent No. 6,045,996, issued 4 April 2000) as defined by Giancoli, D.C. (Physics: Principles with Applications, 3rd ed. Prentice Hall, NJ, 1991, page 782).

Regarding Claim 13, Cronin et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a solvent containing at least one betaine and applying the nucleic acid-betaine solution to the carrier whereby the nucleic acids are bound to the carrier via hydrogen bonding to probes immobilized on the carrier (Column 10, line 48-Column 11, line 20). While the claims do not require methods steps of covalent attachment, the hydrogen bonds are defined by Giancoli as "partially covalent" (page 782). Therefore, the

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immobilized nucleic acids of Cronin are partially covalently bound and therefore are encompassed by the non-limiting preamble of the instant claim.

Regarding Claim 14, Cronin et al disclose the process wherein the betaine is trimethylammonium acetate (Column 4, lines 22-31).

Regarding Claim 15, Cronin et al disclose the process wherein the betaine is present at a concentration of 8mM to 6.5M (Column 4, lines 3-31 and Column 5, lines 11-12).

Regarding Claim 17, Cronin et al disclose the process wherein the carrier is made of glass (Column 10, lines 17-19).

Regarding Claim 24, Cronin et al disclose a process for binding nucleic acids to a carrier comprising adding a betaine to a solution of nucleic acids and subsequently applying the solution to a carrier to bind the nucleic acids to the carrier via hybridization (Column 10, line 48-Column 11, line 20). While the claims do not require methods steps of covalent attachment, the hydrogen bonds are defined by Giancoli as "partially covalent" (page 782). Therefore, the immobilized nucleic acids of Cronin are partially covalently bound and therefore are encompassed by the non-limiting preamble of the instant claim.

Regarding Claim 25, Cronin et al disclose a process comprising the steps of dissolving nucleic acids and a betaine in a solvent to obtain a solution, applying the solution to onto microarray to bind the nucleic acids to the surface of the microarrays via hybridization (Column 10, line 48-Column 11, line 20). While the claims do not require methods steps of covalent attachment, the hydrogen bonds are defined by Giancoli as "partially covalent" (page 782). Therefore, the immobilized nucleic acids of Cronin are partially covalently bound and therefore are encompassed by the non-limiting preamble of the instant claim.

Regarding Claim 26, Cronin et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids and a betaine in a solvent to obtain a solution of nucleic acids and betaines and applying the solution to a carrier to bind the nucleic acids to the carrier via hybridization (Column 10, line 48-Column 11, line 20). While the claims do not

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require methods steps of covalent attachment, the hydrogen bonds are defined by Giancoli as "partially covalent" (page 782). Therefore, the immobilized nucleic acids of Cronin are partially covalently bound and therefore are encompassed by the non-limiting preamble of the instant claim.

Response to Arguments

10. Applicant argues that Cronin teaches the use of arrays in hybridizing nucleic acids but does not teach the use of a betaine solution for the production of arrays or for binding nucleic acids to the surface of a carrier. The argument has been considered but is not found persuasive because, the instant claims are drawn to methods comprising the steps of dissolving nucleic acids in a solution and apply the solution to a carrier (or microarray) for binding thereto. The methods do not include method steps of microarray production as asserted. Therefore, the arguments are not commensurate in scope with the claims.

11. Claims 13-15, 17, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Koster (U.S. Patent No. 5,547,835, issued 20 August 1996).

Regarding Claim 13, Koster discloses a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67) wherein the nucleic acids are covalently bound to the support via thiol-modified or amino-modified nucleic acids coupling to thiolated supports (Column 21, lines 37-39 or 50-67).

Regarding Claim 14, Koster discloses the process wherein the betaine is trimethylammonium acetate (TEAA) (Column 21, lines 39-67).

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Regarding Claim 15, Koster discloses the process wherein the betaine is present in a spotting solution at a concentration range of 8mM to 6.5M (Column 21, lines 39-67).

Regarding Claim 17, Koster discloses the process wherein the carrier is made of glass (Column 14, lines 5-10).

Regarding Claim 24, Koster discloses a process for binding nucleic acids to a carrier comprising adding betaine to a solution of nucleic acids to produce a solution containing nucleic acids and betaine and applying the solution to a carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67).

Regarding Claim 26, Koster discloses a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution to produce a solution containing nucleic acids and betaine and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67).

Response to Arguments

12. Applicant argues that Koster does not teach the instantly claimed covalent or electrostatic binding of nucleic acids. The argument has been considered but is not found persuasive. As stated above, the instant claims do not recite method steps of covalent or electrostatic binding. Therefore, the argument is not commensurate in scope with the claims. Furthermore, Koster does teach covalent attachment via thiol-modified or amino-modified nucleic acids coupling to thiolated supports (Column 21, lines 37-39 or 50-67).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 16, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (U.S. Patent No. 5,547,835, issued 20 August 1996) in view of DeRisi et al (Science, 24 October 1997, 278: 680-686).

Regarding Claim 16, Koster teaches the process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67) wherein the betaine/nucleic acid solution in a buffered solution at about pH 7 (Column 21, lines 58-67) but they do not teach the buffer is sodium chloride and sodium citrate (SSC). However, SSC was routinely practiced in the art as a buffer for spotting solutions as taught by DeRisi et al (page 685, ¶ 9). While DeRisi et al do not teach the specific concentrations of SSC, it would have been obvious to one of ordinary skill in the art to use routine experimentation to derive optimal concentrations to thereby maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the SSC buffer of DeRisi et al to the buffered solution of Koster to thereby effectively spot the nucleic acids onto the carrier as taught by DeRisi (page 685, ¶ 9).

Regarding Claims 18-20, Koster teaches the process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67) wherein the carrier is made of glass (Column 14, lines 5-10) but they do not teach coating the glass carrier. However, it was well known in the art at the time the claimed invention was made that glass

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carriers for nucleic acids were coated with poly-L-lysine as taught by DeRisi et al (page 685, ¶ 9). DeRisi et al further teach that the glass carrier is further treated with a solution of succinic anhydride and an acylating catalyst in a nonpolar non-aqueous solvent to thereby block non-specific binding (page 685, ¶ 9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the poly-L-lysine coating followed by treatment with succinic anhydride and an acylating catalyst as taught by DeRisi et al to the glass carrier of Koster for the expected benefit of effectively immobilizing nucleic acids and blocking non-specific binding as taught by DeRisi et al (page 685, ¶ 9).

Response to Arguments

15. Applicant reiterated the arguments regarding Koster and further asserts that DeRisi does not teach the elements missing in Koster. The arguments have been considered but are not found persuasive for the reasons stated above regarding Koster.

NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

16. This application contains sequence disclosures (page 12) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN A PERIOD OF TIME WHICH IS COEXTENSIVE WITH THE TIME TO REPLY TO THE ABOVE OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time

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may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Response to Comments

17. Applicant asserts that the instant applicant does not require a sequence listing. The assertion is noted. However, Applicant has not provided any reasoning for the assertion. The instant specification as page 12, recites a nucleic acid sequence. The sequence must be identified by a "SEQ ID NO:" and provided in a sequence listing. Alternatively, Applicant may delete the sequence from the specification. Applicant is reminded that new matter cannot be added to the specification. It is suggested that Applicant review 37 C.F.R. § 1.821-1.825.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 3, 2004